

CLAIMS

The claims as pending are as follows:

1. (previously presented): A composition comprising a soluble, substantially integral bARE class protein, arginine phosphate and 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS), wherein the bARE class protein is an AB5 cholera toxin (CT) ADP-ribosylating toxin or an AB5 *E. coli* heat labile toxin (LT).

2 to 4. (canceled).

5. (previously presented): The composition according to claim 1, wherein the Arginine phosphate is present in an amount of from about 100mM to about 400mM.

6 to 9. (canceled)

10. (previously presented): The composition according to claim 1, wherein the 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS) is present in an amount of from about 0.05% to about 0.5% by weight per volume (w/v).

11. (canceled).

12. (previously presented): The composition according to claim 1, wherein the ratio of integral bARE protein to dissociated A and B forms is at least 2:1.

13. (canceled)

14. (previously presented): The composition according to claim 1, wherein the bARE protein is an LTK63 or LTK 72 protein.

15. (withdrawn): A method of stabilising a bARE protein, wherein the method comprises providing a bARE class protein according to claim 1 and combining the bARE class protein with a stabilising agent.

16 and 17. (canceled)

18. (withdrawn): The method according to claim 15, wherein the Arginine or Arginine phosphate is present in an amount of from about 100mM to about 400mM.

19 to 22. (canceled)

23. (withdrawn): The method according to claim 15, wherein the 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS) is present in an amount of from about 0.05% to about 0.5% by weight per volume (w/v).

24. (canceled)

25. (withdrawn): The method according to claim 15, wherein the ratio of integral bARE protein to dissociated A and B forms is at least 2:1.

26. (canceled).

27. (withdrawn): The method according to claim 15, wherein the AB5 protein is an LTK63 or LTK 72 protein.

28. (withdrawn): A method of analysing a bARE class protein according to claim 1, the method comprising analysing a composition comprising the bARE class protein under non-dissociating conditions to differentiate between integral and dissociated bARE class proteins.

29. (withdrawn): The method according to claim 28, wherein the method comprises separating the proteins using a charged polymeric separation material.

30. (withdrawn): The method according to claim 29, wherein the polymeric separation material is a hydrogel monomer.

31. (withdrawn): The method according to claim 30, wherein the hydrogel monomer is a hydroxylated polymethacrylate (HEMA) monomer.

32. (withdrawn): The method according to claim 31, wherein the HEMA has a particle size of about 6 microns.

33. (withdrawn): The method according to claim 31, wherein the HEMA has a porosity of about 250A.

34. (withdrawn): A method of analysing a bARE class protein wherein the method comprises:

(i) applying a bARE class protein to a charged polymeric separation material in an apparatus configured to resolve an integral bARE class protein according to claim 1 from a dissociated bARE class protein;

(ii) treating the separation material comprising the applied bARE class protein with an ionic buffer; and

(iii) detecting one or more integral or dissociated bARE class proteins.

35. (withdrawn): The method according to claim 34, wherein the separation material is a hydrogel monomer.

36. (withdrawn): The method according to claim 34, wherein the ionic buffer is a physiologically acceptable buffer with a pH of from about 7.0 to about 8.0.

37. (withdrawn): A method for identifying a bARE class protein stabilisation agent wherein the method comprises:

- (i) combining a bARE class protein according to claim 1 with a candidate stabilising agent to form a bARE protein sample;
- (ii) applying the bARE protein sample to a charged polymeric separation material in an apparatus configured to resolve an integral bARE class protein from a dissociated bARE class protein;
- (iii) treating the separation material comprising the applied bARE class protein with an ionic buffer;
- (iv) detecting one or more integral or dissociated bARE class proteins; and
- (v) determining whether the candidate stabilising agent is a bARE protein stabilising agent.

38. (withdrawn): The method according to claim 37, wherein the method comprises calculating an Integrity Ratio for the bARE protein sample.

39. (withdrawn): The method according to claim 38, wherein the method further comprises comparing the Integrity Ratio for the bARE protein sample with an Integrity Ratio for a control without a candidate stabilising agent.

40. (withdrawn): A stabilising agent identified by the method of claim 37.

41. (withdrawn): The stabilising agent according to claim 40, which is a functional stabilising agent.

42. (withdrawn): The stabilising agent according to claim 40, which is a physical stabilising agent.

43. (previously presented): An immunogenic composition comprising a composition according to claim 1.

44. (original): An immunogenic composition according to claim 43, wherein further comprising an adjuvant, wherein said adjuvant is not the bARE protein.

45. (original): An immunogenic composition according to claim 44, wherein the adjuvant is a mucosal adjuvant.

46. (canceled).

47. (withdrawn): A method of treating a mammal to prevent and/or treat an immune disorder comprising administering a composition according to claim 43.

48. (withdrawn): A method according to claim 47 wherein the mammal is a human.

49 to 60. (canceled).